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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,011	02/09/2007	Reiko Tanaka	Q92322	1047

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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
08/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,011	TANAKA, REIKO	
	Examiner	Art Unit	
	Gregg Polansky	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/23/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-2 are under consideration.

2. Applicants' Information Disclosure Statement, filed 12/23/2005, is acknowledged and has been reviewed.

3. Applicants' Declaration, filed on 2/09/2007, is acknowledged.

Drawings

4. The drawing (flowchart labeled "Scheme" on page 11 of the Specification) is objected to because it is not in compliance with 37 CFR 1.84. The drawing in the instant application is currently contained within the Specification. Correction is required to place the drawing on a separate sheet of paper. Additionally, the current drawing should have a more descriptive title, such as, for example, "Compound 1 Extraction and Purification Flowchart". A corrected drawing sheet in compliance with 37 CFR 1.121(d) is required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicants will be notified

and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The Specification is objected to because: A reference to and brief description of the drawing (flowchart labeled "Scheme", *supra*) as set forth in 37 CFR 1.74 is required.

Appropriate correction is required.

6. The disclosure is objected to because the "Sum of Tumors" column headings in Tables 1 and 2 (pages 14-15) are not explained.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling for Compound 1 **reducing the number of rats developing lung carcinomas** at a dose of 5 mg/kg, it is not enabling for Compound 1 **reducing the number of rats developing lung carcinomas** at a dose of 10 mg/kg, or **reducing the number of rats developing lung adenomas** at any dose. Additionally, while the Specification is enabling for Compound 1

reducing the number of lung adenomas (i.e., reducing the number of lung adenomas in rats developing lung adenomas) at both doses, and the **number of lung carcinomas** at 5 mg/kg, it not enabling for Compound 1 **reducing the number of lung carcinomas** at 10 mg/kg. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention, (2) the breadth of the claims:

The claims are drawn to a method for suppressing or inhibiting lung tumorigenesis, comprising orally administering to a subject in need, an effective amount of a compound (Compound 1) represented by formula (I) in Claim 1. The disclosure does not provide any insight as to a proposed mechanism of action for

Compound 1. The Specification discloses a Compound 1 dose range of 0.1 mg/day to 2000 mg/day (*see* page 7, line 1). This is a dose range of 0.0014 mg/kg to 28.6 mg/kg for a 70 kg subject. This is a 4 orders of magnitude difference between the lowest and highest doses.

(3) The relative skill of those in the art:

The relative skill in the art is that of a medical doctor/oncologist.

(4) The amount of direction or guidance presented and (5) the presence or absence of working examples:

The Specification provides an example of the suppression/inhibition of lung tumorigenesis in rats treated with Compound 1. The results are provided in Specification Tables 1 and 2 and are summarized above. The Examiner has noted that in the example provided, the control group did not receive a sham treatment (i.e., administration of the corn oil carrier without Compound 1). Without this control, it is not possible to rule out anti-tumorigenic activity of the carrier oil.

(6) The state of the prior art and (7) the predictability or unpredictability of the art:

There appears to be no prior art on the suppression or inhibition of lung tumorigenesis by Compound 1. Given the lack of guidance from prior art, the seemingly greater effectiveness of Compound 1 at the lower of the two doses used in the example, and the very wide dose range recited in the Specification

(especially in comparison with the very narrow dose range of the example), one skilled in the art would reasonably conclude the claimed method is unpredictable.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, the lack of adequate guidance provided in the specification as exemplified by the inconsistency of tumorigenesis suppression in the working example, the very broad dose range recited in the Specification, and the high unpredictability in the art as evidenced therein, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Conclusion

8. Claims 1-2 are rejected.

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on Mon-Thur 8:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GP

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER

8/17/07